Article 13. – COMPOUNDING

68-13-1. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642; effective May 1, 1988; amended Feb. 7, 2003; revoked P-_____.)

68-13-2. Definitions. (a) "Beyond-use date" means a date placed on a prescription label at the time of dispensing, repackaging, or prepackaging that is intended to indicate to the patient or caregiver a time beyond which the contents of the prescription are not recommended to be used.

(b) "Biological safety cabinet" means a containment unit suitable for the preparation of low-risk to high-risk agents, when there is a need for protection of the product, personnel, and environment, that meets the requirements in national sanitation foundation international standard 49, "class II (laminar flow) biosafety cabinetry," NSF/ANSI 49-2004a, and its annexes, revised September 2004, and its addendum, 2.0-2004, revised March 2005, both of which are adopted by reference.

(c) "Component" means any ingredient intended for use in the compounding of a drug product, including any ingredient that does not necessarily appear in the list of ingredients for the drug product.

(d) "Compounding" means the combining of components into a compounded preparation under either of the following conditions:

(1) As the result of a practitioner's prescription drug order or initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice to meet the specialized medical need of an individual patient of the practitioner that cannot be filled by an FDA-approved drug; or

(2) for the purpose of, or incident to, research, teaching, or chemical analysis and not for sale or dispensing.

Compounding shall include the preparation of drugs or devices in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns. Compounding shall not include reconstituting an oral or topical drug according to the FDA-approved labeling for the drug.

(e) "Compounding area" means any area in a pharmacy where compounding is performed.

(f) "Cytotoxic," when used to describe a pharmaceutical, means that the pharmaceutical has the capability of killing living cells. This term shall also be used to describe components classified as cancer chemotherapeutic, carcinogenic, mutagenic, and antineoplastic.

(g) "Essentially a copy of a commercially available drug product" shall not include any drug product to which there is a change made for an identified individual patient that produces for that patient a significant therapeutic difference, as determined by the prescribing practitioner, between the compounded drug and a comparable, commercially available drug product.

(h) "Order" means either a prescription order as defined in K.S.A. 65-1626(cc), and amendments thereto, or a medication order as defined in K.A.R. 68-5-1(c).

(i) "Parenteral," when used to refer to a solution, means that the solution is administered by injection through one or more layers of skin, or other routes of administration that bypass the gastrointestinal tract.

(j) "Parenteral product" means a preparation administered by injection through one or more layers of skin.

(k) "Practitioner-patient-pharmacist relationship" means a relationship that meets all of the following conditions:

(1) The practitioner has assumed the responsibility for making medical judgments regarding the health of the patient and the need for medical treatment.

(2) The practitioner has sufficient knowledge of the patient to initiate at least a general or preliminary diagnosis of the medical condition, and the practitioner has examined the patient and is available for follow-up.

(3) The practitioner has communicated the necessary prescriptions to the pharmacist, who is able to provide pharmaceutical care to the patient and communicate with the practitioner if needed. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 2007 Supp. 65-1642; effective P- _____.)

68-13-3. Nonsterile compounded preparations. (a) This regulation shall apply to nonsterile compounded preparations that are compounded in Kansas and to nonsterile compounded preparations that are compounded outside Kansas and are to be administered to any patient within Kansas.

(b) A pharmacist shall not prepare a nonsterile compounded preparation that is essentially a copy of a commercially available drug product.

(c) A pharmacist shall not prepare any nonsterile compounded preparation by any of the following methods:

(1) Using any component that has been withdrawn from the market by the food and drug administration for safety reasons or that is deemed unsafe by the food and drug administration and listed in the current code of federal regulations;

(2) receiving, storing, or using any drug components that are not guaranteed or otherwise determined to meet official compendia requirements; or

(3) compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs without first receiving an FDA-sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. 355(i) and 21 CFR Part 312 and amendments thereto.

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(d) Any pharmacist may prepare a nonsterile compounded preparation before receiving a valid order if the pharmacist has previously filled orders for the nonsterile preparation generated as part of an established practitioner-patient-pharmacist relationship, demonstrating a need to prepare the nonsterile preparation before receiving an order, for the convenience of the patient.

(e) A pharmacist shall not knowingly sell any nonsterile compounded preparation to a practitioner, pharmacist, or pharmacy if the pharmacist knows or should have known that the purchaser's intent is to resell, dispense, or distribute the nonsterile compounded preparation, except that a pharmacist may sell a nonsterile compounded preparation to a practitioner who intends to administer the nonsterile compounded preparation to a patient. Each nonsterile compounded preparation sold by a pharmacist to a practitioner for administration to a patient shall be packaged with a label that includes the statement "For Office Use Only – Not For Resale." The distribution of nonsterile compounded preparations without a practitioner-patient-pharmacist relationship shall be considered manufacturing.

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(f) Within each pharmacy in which compounding occurs, one area shall be designated as the principal compounding area, where all compounding shall take place. In addition to the principal compounding area, there may be one or more satellite compounding areas that are a part of the same pharmacy. The principal compounding area and any satellites shall meet the following requirements:

(1) All compounding areas shall be well-lighted and well-ventilated with clean and sanitary surroundings, free of food and beverages, that are devoted primarily to compounding. These areas shall provide the drugs, chemicals, and devices with the necessary protection from deterioration due to light, heat, and evaporation and shall be arranged to protect all prescription drugs and devices from pilferage and any other unauthorized removal.

(2) All components used in the compounding of drug products shall be stored in labeled containers in a clean, dry area or, if required, under proper refrigeration.

(3) A sink for hand and equipment washing shall be available and shall be equipped with hot and cold running water.

(4) Purified water shall be used for compounding nonsterile compounded preparations when the formulations indicate the inclusion of water.

(g) For each nonsterile compounded preparation, a uniform, readily retrievable formulation record shall be maintained, documenting the following:

(1) The ingredients, quantities, strength, and dosage form of the preparation compounded;

(2) the equipment used to prepare the preparation and the mixing instructions;

(3) the container used in dispensing;

(4) the storage requirements;

(5) the beyond-use date to be assigned;

(6) quality control procedures, which may include monitoring the following:

(A) Capsule weight variation;

(B) adequacy of mixing to ensure uniformity and homogeneity; and

(C) the clarity, completeness, or pH of solutions;

(7) the source of the formulation, including the name of the person, entity, or publication; and

(8) the name of the pharmacist who verified the accuracy of the formulation record and the date of verification.

(h) For each nonsterile compounded preparation, a compounding record shall be maintained on the original prescription or medication order or on a separate, uniform, readily retrievable record documenting the following:

(1) The name and strength of the preparation;

(2) the identifier used to distinguish the preparation's formulation record from other formulation records;

(3) the name of the manufacturer, and, if applicable, the lot number and the expiration date of each component;

(4) the total number of dosage units compounded;

(5) the name of the person, or persons, who prepared the preparation;

(6) the name of the pharmacist, pharmacy student, or intern working under the direct supervision and control of the pharmacist who verified the accuracy of the preparation;

(7) the date of compounding;

(8) the assigned internal identification number, if used;

(9) the assigned beyond-use date. In the absence of valid scientific stability information that is applicable for a component or the compounded preparation, the beyond-use date shall be established in accordance with the following criteria:

(A) For nonaqueous and solid formulations, either of the following:

(i) If a manufactured drug product is the source of the active ingredient, six months from the date of compounding or the time remaining until the manufactured drug product's expiration date, whichever is earlier; or

(ii) if a substance found in the "United States pharmacopeia-national formulary" is the source of an active ingredient, either six months from the date of compounding or the time remaining until the substance's expiration date, whichever is earlier;

(B) for water-containing formulations prepared from ingredients in solid form, not more than 14 days when stored under refrigeration; and

(C) for all other formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier;

(10) the prescription number, if assigned; and

(11) the results of quality control procedures.

This compounding record and the corresponding formulation record specified in subsection (g) shall be retained and readily available for inspection by the board at the compounding pharmacy for at least five years.

(i) The pharmacist-in-charge shall be responsible for ensuring that, before performing delegated compounding, all support personnel are trained and can successfully demonstrate the following:

(1) Comprehensive knowledge of the pharmacy's standard operating procedures with regard to compounding as set forth in the policy and procedure manual; and

(2) familiarity with the compounding techniques used in the pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 2007 Supp. 65-1642; effective P-_____.)

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68-13-4. Sterile compounded preparations. (a) This regulation shall apply to sterile compounded preparations that are compounded in Kansas and also to sterile compounded preparations that are compounded outside Kansas and are to be administered to a patient within Kansas.

(b) Definitions. As used in this regulation, the following words shall have the meanings specified:

(1) "Barrier isolation chamber" means an apparatus that meets each of the following specifications:

(A) Is designed to provide an international standards organization class five environment for the preparation of sterile products;

(B) uses solid chamber walls rather than air movement to create a critical area for product handling;

(C) has a high-efficiency particulate air (HEPA) filtration system that conditions the air flowing through the unit to remove initial airborne particles and airborne particles generated within the controlled environment; and

(D) has a means by which products are introduced into the critical area and people interact with the product being prepared within the apparatus without breaking the seals of the chamber walls.

(2) "Batch" means multiple sterile dosage units in a quantity greater than 25 that are compounded in a discrete process by the same individuals during one limited time period.

(3) "Class five environment" means an atmospheric environment that contains less than 3,520 airborne particles measuring 0.5 micron in diameter per cubic meter of air.

(4) "Class seven environment" means an atmospheric environment that contains less than 352,000 airborne particles measuring 0.5 micron in diameter per cubic meter of air.

(5) "Class eight environment" means an atmospheric environment that contains less than 3,520,000 airborne particles measuring 0.5 micron in diameter per cubic meter of air.

(6) "Sterile compounded preparation" means a preparation compounded using currently accepted aseptic compounding techniques under acceptable compounding conditions. This term shall include any commercially prepared sterile drug dosage form that has been altered in the compounding process.

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(7) "Controlled area" means an area that is designated for preparing sterile compounded preparations and that provides a buffer between the surrounding environment and the critical area.

(8) "Critical area" means any area in the controlled area where components, compounded products, or containers are exposed to the environment.

(9) "Dosage unit" means the amount of a compounded sterile preparation that would be administered to or taken by one patient at one time.

(10) "Endotoxin" means a potentially toxic, natural compound that is a structural component of bacterial cell walls and that are released mainly when bacteria are lysed.

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(11) "Immediate use" means a situation in which a preparation is compounded in a medical care facility pursuant to a medication order immediately before administration to the patient, the

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Immediate use sterile compounds may be prepared outside the laminar flow hood if the following requirements are met:

(A) The preparation of the sterile compound takes no longer than one hour;

(B) the administration of the sterile compound begins within one hour after preparation;

(C) the sterile compound is administered during a period that is less than 24 hours; and

(D) the sterile compound is prepared by a closed-system aseptic transfer of sterile, nonpyrogenic finished pharmaceuticals obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers.

(12) "Laminar airflow hood" means an apparatus designed to provide a class five environment for the preparation of sterile products using air circulation in a defined direction that passes through a high-efficiency particulate air (HEPA) filter.

(13) "Low-risk," when used to describe any compounded sterile preparation, means that the preparation meets the following conditions:

(A) In the absence of sterility testing, is stored at room temperature and completely administered within 48 hours from preparation, is stored under refrigeration for 14 days or less before complete administration to a patient over a period not to exceed 24 hours, or is frozen for 45 days or less at -20°C or colder before complete administration to a patient over a period not to exceed 24 hours;

(B) is an unpreserved sterile preparation prepared for administration to one patient or is a batch-prepared preparation containing suitable preservatives for administration to more than one patient;

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(C) is prepared by closed-system aseptic transfer of no more than three sterile, nonpyrogenic, finished pharmaceuticals obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers with no more than two instances in which a transfer devices passes through the septum or designated entry point into any one sterile container or package; and

(D) is compounded by no more than three manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container obtained from a licensed manufacturer by using a closed-system aseptic transfer.

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This term shall apply to single-patient admixtures, single-patient ophthalmic preserved solutions, single-patient syringes without preservatives used within 48 hours, and batch-filled syringes with preservatives.

(14)(A) "Medium-risk," when used to describe any compounded sterile preparation, means that the preparation meets one or more of the following conditions:

(i) In the absence of sterility testing, is stored at room temperature and administered beyond 30 hours after preparation, is stored under refrigeration for more than nine days, or is stored frozen at -20°C or colder for more than 45 days;

(ii) is batch-prepared without preservatives and is intended for use by more than one patient or for use by one patient on multiple occasions;

(iii) is created by a compounding process that includes complex aseptic manipulations other than the single-volume transfer;

(iv) does not contain broad-spectrum bacteriostatic substances and is administered over several days; or

(v) is compounded by at least four manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container obtained from a licensed manufacturer by using a closed-system aseptic transfer.

(B) This term shall apply to the following:

(i) Preparations for use in a portable pump or reservoir over multiple days;

(ii) batch-reconstituted antibiotics without preservatives;

(iii) batch-prefilled syringes without preservatives; and

(iv) total parenteral nutrient solutions that are made by the gravity transfer of carbohydrates and amino acids into an empty container with the addition of sterile additives using a syringe and needle or that are mixed with an automatic compounding device.

(15)(A) “High-risk,” when used to describe a sterile compounded preparation, means that the preparation meets one or more of the following conditions:

(i) The preparation is compounded from nonsterile ingredients or with nonsterile containers or equipment before terminal sterilization.

(ii) The sterile ingredients or components of the preparation are exposed to air quality inferior to class five.

(iii) The nonsterile ingredients or components of the preparations are exposed to air quality inferior to class five for at least six hours before being sterilized.

(iv) The compounding pharmacist cannot verify from documentation received from the supplier or by direct examination that the chemical purity and content strength of the ingredients meet their original or compendial specifications.

(v) The compounded preparation has been stored at room temperature and administered beyond 24 hours after preparation, stored under refrigeration more than three days, or stored frozen at -20°C or colder for more than 45 days, and sterility has not been confirmed by testing.

(B) This term shall apply to preparations including the following:

(i) Alum bladder irrigation solution;

(ii) any morphine preparation made for parenteral administration from nonsterile powder or tablets;

(iii) any total parenteral nutrition solution made from dried amino acids;

(iv) any total parenteral nutrition solution sterilized by final filtration; and

(v) any autoclaved intravenous solution.

(16) "Media fill test" means a test in which a microbiological growth medium such as soybean-casein digest medium is substituted for the actual drug product to simulate admixture compounding. The media fill test is passed if person and process used to perform aseptic technique of compounding produces a sterile product without microbial contamination. During this test,

(17) "Multiple-dose container means a multiple-unit container for any preparation intended for parenteral administration only and usually containing antimicrobial preservatives. The

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beyond-use date for an opened or entered multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

(18) "Segregated compounding area means a designated space, either a demarcated area or room that is restricted to preparing low-risk level compounded sterile products.

(19) "Single-dose container" means a single-unit container for any preparation intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Single-dose containers shall be used within one hour if opened in worse than ISO Class 5 air quality and any remaining contents must be discarded. Single-dose containers exposed to ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture.

(c) Once a multiple-dose-container with antimicrobial preservatives has been opened or entered, the container shall be labeled with a beyond-use date not to exceed 28 days, unless otherwise specified by the manufacturer.

(d) A segregated compounding area shall contain a device that provides unidirectional airflow of Class 5 air quality for the preparation of compounded sterile products and shall be void of all activities and materials that are extraneous to sterile compounding.

(e) A compounded sterile product compounded in a segregated compounding area shall be labeled with a beyond-use date of no more than 12 hours.

(f) A single-dose container shall be labeled as such.

(g) The contents of a single-dose container shall be used within one hour if the container is opened or entered in an area with air quality that does not meet the requirement of a class five environment.

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(h) The contents of a single-dose container shall be used within six hours if the container is opened or entered in an area with air quality that meets the requirement of a class five environment.

(i) Any pharmacist may compound a sterile preparation before receiving a valid order if the pharmacist has previously filled orders for the sterile preparation generated as part of an established practitioner-patient-pharmacist relationship, demonstrating a need to prepare the sterile preparation before receiving an order, for the convenience of the patient.

(j) A pharmacist shall not knowingly sell any compounded sterile preparation to a practitioner, pharmacist, or pharmacy if the pharmacist knows or should have known that the purchaser's intent is to resell, dispense, or distribute the compounded sterile preparation, except that a pharmacist may sell a compounded sterile preparation to a practitioner who intends to administer the compounded sterile preparation to a patient. Each compounded sterile preparation sold by a pharmacist to a practitioner for administration to a patient shall be packaged with a label that includes the statement "For Office Use Only – Not For Resale." The distribution of sterile compounded preparations without a practitioner-patient-pharmacist relationship shall be considered manufacturing.

(k) A pharmacist shall not prepare any sterile compounded preparation that is essentially a copy of a commercially available drug product.

(l) A pharmacist shall not prepare any sterile compounded preparation by any of the following methods:

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(1) Using any component that has been withdrawn from the market by the food and drug administration for safety reasons or that is deemed unsafe by the food and drug administration and listed in the current code of federal regulations;

(2) receiving, storing, or using any drug component that is not guaranteed or otherwise determined to meet official compendia requirements; or

(3) compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs without first receiving an FDA-sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. 355(i) and 21 CFR Part 312.

(j) Each pharmacist or pharmacy engaged in the preparation and compounding of sterile preparations shall have available the following resources:

(l) A laminar airflow hood, barrier isolation chamber, or other suitable class five environment that is currently certified by a licensed inspector to ensure aseptic conditions within the working area and that has the required documentation. The certification shall be deemed current if the certification occurred within the previous six months or on the date the device was last moved to another location, whichever is less. The required documentation shall include the following:

(A) Inspection certificates for the past five years or since the date of installation, whichever is less;

(B) a record of all filter maintenance;

(C) a record of all high-efficiency particulate air filter maintenance; and

(D) a record of all disinfecting and cleaning;

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(2) a sink;

(3) a refrigerator capable of maintaining a temperature of 2° to 8°C (36° to 46°F) and a freezer, if needed, capable of maintaining a temperature of -25° to -10°C (-13° to 14°F). The temperature shall be monitored and recorded each business day. Each pharmacy with an electronic system that alerts the pharmacist to noncompliant temperatures shall be exempt from daily recording;

(4) the reference materials required by K.A.R. 68-2-12a and a current copy of a reference text on intravenous incompatibilities and stabilities. If an electronic library is provided, a workstation shall be readily available for use by pharmacy personnel, students, interns, and board personnel;

(5) a policy and procedure manual, with an annually documented review by the pharmacist-in-charge or designee, which shall include the following subjects:

(A) Sanitation;

(B) storage;

(C) dispensing;

(D) labeling;

(E) destruction and return of controlled substances;

(F) recordkeeping;

(G) recall procedures;

(H) responsibilities and duties of supportive personnel;

(I) aseptic compounding techniques; and

(J) ongoing evaluation procedures for all staff making the preparations; and

(6) supplies necessary for sterile product compounding.

(k) For each sterile compounded preparation, a uniform, readily retrievable formulation record shall be maintained, documenting the following:

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(1) The quantities, strength, and dosage form of all components of the preparation compounded;

(2) the equipment used to prepare the preparation and the mixing instructions;

(3) the container used in dispensing;

(4) the storage requirements;

(5) the beyond-use date to be assigned;

(6) quality control procedures, which may include monitoring the following, if applicable:

(A) Adequacy of mixing to ensure uniformity and homogeneity;

(B) the clarity, completeness, or pH of solutions;

(7) the sterilization methods;

(8) the source of the formulation; and

(9) the name of the pharmacist who verified the accuracy of the formulation record and the date of verification.

(l) For each sterile compounded preparation, a compounding record shall be maintained on the original prescription or medication order, or on a separate, uniform, readily retrievable record documenting the following:

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(1) The name and strength of the sterile compounded preparation;

(2) the formulation record reference for the sterile compounded preparation;

(3) the name of the manufacturer, and, if applicable, the lot number and the expiration date of each component;

(4) the total number of dosage units compounded;

(5) the name of the person or persons who compounded the sterile preparation;

(6) the name of the pharmacist or the pharmacy student or intern working under the direct supervision and control of the pharmacist who verified the accuracy of the preparation;

(7) the date of preparation;

(8) the assigned internal identification number, if applicable;

(9) the assigned beyond-use date. In the absence of valid scientific stability information that is applicable for a component or the sterile compounded preparation, the beyond-use date shall be established in accordance with the following criteria:

(A) For nonaqueous and solid formulations, one of the following:

(i) If the manufactured drug product is the source of the active ingredient, six months or the time remaining until the product's expiration date, whichever is earlier;

(ii) if a substance listed in the "United States pharmacopeia-national formulary" is the source of the active ingredient, six months or the time remaining until the substance's expiration date, whichever is earlier;

(B) for water-containing formulations prepared from ingredients in solid form, not more than 14 days when stored under refrigeration; or

(C) for all other formulations, not longer than the intended duration of therapy or 30 days, whichever is earlier;

(10) the prescription number, if applicable;

(11) the results of the quality control procedures; and

(12) the results of the sterility testing and, if applicable, pyrogen testing for the batch.

The compounding record and corresponding formulation record shall be retained for at least five years and readily available for inspection by the board in the pharmacy where prepared.

Medical care facilities shall be required to generate a compounding record and a corresponding formulation record only when batch compounding.

(m) Each person involved in the preparation of any compounded sterile product shall follow personal garbing and washing procedures that include the following at a minimum:

(1) Preparing for garbing by the removal of outer garments, cosmetics, jewelry, and artificial nails;

(2) performing the following procedures, in the order listed: donning dedicated shoes or shoe covers, donning head a facial hair covers, washing the hands with soap for no less than 20 seconds, and donning a nonshedding gown; and

(3) entering the work area and performing an antiseptic hand-cleaning procedure using a waterless alcohol-based surgical hand scrub and donning sterile, powder-free gloves. Sterile gloves shall be disinfected with 70% isopropyl alcohol after touching any nonsterile area.

(n) All sterile compounded preparations shall be stored and delivered in a manner that is designed to maintain parenteral product stability and sterility.

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(o) All sterile compounded preparations, except any preparations compounded for immediate use, shall be prepared under aseptic conditions as follows:

(1) Each low-risk sterile compounded preparation labeled with a beyond-use date of 12 hours or longer shall be prepared in a class five environment critical area using techniques that ensure sterility. Each low-risk sterile compounded preparation labeled with a beyond-use date of less than 12 hour shall at a minimum be prepared in a segregated compounding area.

(2) Each medium-risk sterile compounded preparation shall be prepared in conformance with the requirements for low-risk sterile compounded preparations and, if not using a barrier isolation chamber, shall have a class seven surrounding controlled area;

(3) Each high-risk sterile compounded preparation shall be prepared in conformance with the requirements for low-risk sterile compounded preparations and, if not using a barrier isolation chamber, shall have a class seven surrounding controlled area. All nonsterile components shall meet United States pharmacopeial and FDA standards for identity, purity, and endotoxin levels as verified by a pharmacist.

The requirements for the controlled area specified in this subsection shall not take effect until the date on which this regulation becomes effective, a new compounding area is constructed, or the compounding area is remodeled, whichever occurs first.

(p) Each pharmacist engaged in the dispensing of sterile compounded preparations shall meet all labeling requirements under state and federal law. In addition, the label of each sterile compounded preparation shall contain the following information:

(l) The name and quantity of each component;

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(2) the beyond-use date;

(3) the prescribed flow rate;

(4) the name or initials of the person who prepared the preparation; and

(5) any special storage instructions.

(q)(1) The pharmacist-in-charge and all personnel involved in compounding sterile preparations shall have practical or academic training in sterile product compounding, clean room technology, laminar flow technology, and quality assurance techniques. This training shall include at least one successful media fill test and be documented for each person before that person begins to compound sterile products. That documentation shall be maintained by the pharmacy for at least five years and shall be made available to the board upon request.

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(2) The pharmacist-in-charge shall be responsible for ensuring that all supportive personnel are trained and successfully demonstrate the following before performing any delegated sterile admixture services:

(A) Comprehensive knowledge of the pharmacy's standard operating procedures with regard to sterile admixture services, as set forth in the policy and procedure manual;

(B) familiarity with the compounding techniques; and

(C) aseptic technique, which shall be proven by means of a test batch.

This training shall be documented for each person before that person begins to compound sterile products. That documentation shall be maintained by the pharmacy for at least five years and shall be made available to the board upon request. Each individual who fails to demonstrate

acceptable aseptic technique shall be prohibited from engaging in sterile product preparation until the individual demonstrates acceptable technique by means of a test batch.

(3) The pharmacist-in-charge shall be responsible for testing the aseptic technique of all personnel involved in sterile product preparation annually by means of a test batch. All personnel involved in high-risk sterile product preparation shall undergo this testing twice each year. The test results shall be maintained for at least five years and shall be made available for the board's inspection upon request. Each individual who fails to demonstrate acceptable aseptic technique shall be prohibited from engaging in sterile product preparation until the individual demonstrates acceptable technique by means of a test batch.

(r) The pharmacist-in-charge shall be responsible for maintaining records documenting the frequency of cleaning and disinfection of all compounding areas, according. To the following minimum requirements:

(1) Class 5 environment areas shall be cleaned and disinfected at the beginning of each shift and every 30 minutes while a compounding process is occurring, before batches, and after spills or known contamination.

(2) the counters, work surfaces and floors shall be cleaned and disinfected daily;

(3) the walls, ceilings and storage shelving shall be cleaned and disinfected monthly.

(s) The pharmacist-in-charge shall be responsible for maintaining records documenting the monitoring of the air pressure and air flow of the ante to buffer areas of the sterile compounding area and initiating immediate corrective action if indicated. The air pressure shall be maintained

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at 5 Pa (0.02 inch water column) and the air flow should be maintained at 0.2 meters per second. The air pressure and air flow values shall be checked and recorded daily at a minimum.

(t) The pharmacist-in-charge shall be responsible for maintaining records documenting the monitoring of the cleanliness and sterility of the sterile compounding environment. Environmental sampling shall be performed in each new facility before a sterile product compounded in that facility is provided to a patient and at a minimum, every six months thereafter. The environmental sampling shall include the hood, room, and equipment and shall be performed following any repair or service being performed on the facility and in response to any identified problems or concerns.

(1) Environmental sampling shall consist of the following, at a minimum:

(A) Environmental nonviable particle counts;

(B) environmental viable airborne particle testing by volumetric collection;

(C) environmental visible surface sampling; and

(D) certification of laminar flow hoods and rooms.

(2) If any one of the following microbial contamination levels is detected in a class five environment, sterile products shall not be compounded until each of the levels is not exceeded:

(A) Environmental air viable particles greater than one colony-forming unit per cubic meter of air;

(B) environmental surface viable particles greater than three colony-forming units per contact plate; or

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(C) fingertip cultures greater than three colony-forming units per contact plate.

(3) If any one of the following microbial contamination levels is detected in a class seven environment, sterile products shall not be compounded until each of the levels is not exceeded:

(A) Environmental air viable particles greater than 10 colony-forming units per cubic meter of air; or

(B) environmental surface viable particles greater than five colony-forming units per contact plate

(4) If any one of the following microbial contamination levels is detected in a class eight or higher environment, sterile products shall not be compounded until each of the levels is not exceeded:

(A) Environmental air viable particles greater than 100 colony-forming units per cubic meter of air; or

(B) environmental surface viable particles greater than 100 colony-forming units per contact plate.

(u) A high-risk sterile compounded preparation must be administered:

(1) Within 24 hours of compounding if stored at room temperature;

(2) within three days if refrigerated; or

(3) within 45 days if stored frozen at -20°C or colder if sterility has not been confirmed by testing. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 2006 Supp. 65-1642; effective P- _____.)

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